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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,239	03/31/1999	STEVEN A. GOLDMAN	19603/1426	8339

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MICHAEL L GOLDMAN ESQ
NIXON HARGRAVE DEVANS & DOYLE LLP
CLINTON SQUARE PO BOX 1051
ROCHESTER, NY 14603

EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	26

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/282,239	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with th corresp ndenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/27/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants cancellation of claims 19, 21, 22, 27 and 28 without prejudice and amendment of claim 29 to include the limitations of previous claim 19 from which it depended, Paper No. 25, 3/27/20032, is acknowledged and has been entered. Claims 25, 26 and 29 are at issue and are present for examination.

Applicants' arguments filed on 3/27/2003, Paper No. 25, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities: On page 11, lines 1-17 of the specification applicants follow this definition by list a number of illustrative possible cell and promoter combinations which can be used in the invention including: mature oligodendrocyte and a cyclic nucleotide phosphodiesterase I promoter, a myelinating oligodendrocyte and a myelin basic core promoter, an oligodendrocyte and a JC virus minimal core promoter, a precursor and a JC virus minimal core promoter or an oligodendrocyte precursor and a cyclic nucleotide phosphodiesterase II promoter. This portion of the specification is objected to for the reference to "a precursor and a JC virus minimal core promoter". It is not clear what possible cell a "precursor" refers to.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 26 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 (25 and 26 dependent on) is indefinite in that it is confusing in the recitation "... wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation." The metes and bounds of those promoters which are encompassed by this limitation and thus the metes and bounds of those cell populations that are encompassed by the instant claims are unclear. As the specification on page 11, line 1-line 17 recites that "Specific" as used herein to describe a promoter, means that the promoter functions only in the chosen cell type, and a chosen cell type can refer to different types of cells, or different stages in the developmental cycle of a cell. there is nothing to suggest that other promoters would not also be included within the scope of these terms and in the art what is considered specific depends on the individual situation as well as the person making the determination. Applicants follow this definition by listing illustrative possible cell and promoter combinations which can be used in the invention, although these are not necessarily "oligodendrocyte specific promoters". Applicants list these illustrative combinations as a mature oligodendrocyte and a cyclic nucleotide phosphodiesterase I promoter, a myelinating oligodendrocyte

and a myelin basic core promoter, an oligodendrocyte and a JC virus minimal core promoter, a precursor and a JC virus minimal core promoter or an oligodendrocyte precursor and a cyclic nucleotide phosphodiesterase II promoter.

Further this recitation is unclear in that claim 29 is drawn to an enriched or purified preparation of cells in which an oligodendrocyte specific promoter functions in all of the cells of the preparation and the oligodendrocyte specific promoters listed in the specification are not associated with mitotically active oligodendrocyte progenitor cells and thus a preparation of cells in which such a promoter is expressed, (i.e. the cyclic nucleotide phosphodiesterase I promoter) presumably does not contain mitotically active oligodendrocyte progenitor cells as these do not express an "oligodendrocyte specific promoter", but rather an "oligodendrocyte precursor specific promoter".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25, 26 and 29 are directed to all enriched or purified preparations of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation (claim 29) wherein

the mitotic oligodendrocyte progenitor cells are from a post-natal (claim 25) or an adult human (claim 26). The specification, however, only provides the representative species of enriched or purified preparations of human mitotic oligodendrocyte progenitor cells, wherein the cyclic nucleotide phosphodiesterase II (P/CNP2) promoter functions in all cells of the enriched or purified preparation, encompassed by these claims (see also above 112 2nd paragraph rejection). The specification also fails to describe additional preparations of human mitotic oligodendrocyte progenitor cells, wherein any oligodendrocyte specific promoter in addition to the P/CNP2 promoter functions in all cells of the enriched or purified preparation. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 25, 26 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enriched or purified preparations of human mitotic oligodendrocyte progenitor cells, wherein the cyclic nucleotide phosphodiesterase II (P/CNP2) promoter functions in all cells of the enriched or purified preparation, does not reasonably provide enablement for any enriched or purified preparations of human mitotic oligodendrocyte progenitor cells, wherein an

oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 25, 26 and 29 are so broad as to encompass any enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation (claim 29) wherein the mitotic oligodendrocyte progenitor cells are from a post-natal (claim 25) or an adult human (claim 26) The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of preparations broadly encompassed by the claims, including all enriched or purified preparations of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells. Since a determination of those promoters which are oligodendrocyte specific (See above 112 2nd paragraph rejection), is necessary for the isolation of the cells of the claimed

preparation, predictability of said promoters useful to obtain the desired cell population, requires a knowledge of and guidance with regard to which promoters are specific for oligodendrocytes. However, in this case the disclosure is limited to those promoters listed in the specification on page 11,lines 1-17, some of which may or may not be encompassed by an "oligodendrocyte specific promoter" (See above 112 2nd paragraph rejection).

The specification does not support the broad scope of the claims which encompass any enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation, because the specification does not establish: those promoters which function specifically in oligodendrocyte cells. Because of this lack of guidance, the extended experimentation that would be required to determine which promoters function specifically in oligodendrocyte cells, it would require undue experimentation for one skilled in the art to arrive at the majority of those preparations of human mitotic oligodendrocyte progenitor cells, as claimed.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those

preparations human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 26 and 29 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al. (U.S. Patent No. 6,361,996 B1).

Rao et al. teach an isolated, pure and homogeneous population of lineage-restricted oligodendrocyte-astrocyte precursor cells which are capable of self-renewal and differentiation into oligodendrocytes and astrocytes and methods of generating, isolating and culturing such oligodendrocyte-astrocyte precursor cells. The specific pure homogeneous population of cells isolated by Rao et al. is illustrated in Figure 1 (See specifically cell type –14, and the supporting text) and while applicants specifically

teach as an example said pure homogeneous preparation of cells as isolated from rat, applicants point out that the invention encompasses all mammalian neuroepithelial stem cells and is not limited to neuroepithelial stem cells from the rat. Mammalian neuroepithelial stem cells can be isolated from human and non-human primates, equines, canines, felines, bovines, porcines, ovines, lagomorphs, and the like. Thus, Rao et al. anticipates a claim to a enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation.

Claims 25 and 26 which are drawn to the preparation of oligodendrocyte progenitor cells of claim 29 are included in this rejection because these product-by-process like limitations do not change the oligodendrocyte progenitor cells of claim 29. Rao further teach that a better understanding of a number of tumors and other diseases in humans could be facilitated by a better understanding of these cell types and the ability to isolate and grow mammalian these cells in vitro, which allows for the possibility of using such stem cells to treat neurological disorders in mammals, particularly humans. Further, such mammalian neuroepithelial stem cells can be used therapeutically for treatment of certain diseases, e.g. Parkinson's Disease, such as by transplantation of such cells into an afflicted individual. Moreover, such cells can still further be used for the discovery of genes and drugs that are useful for treating certain of these diseases.

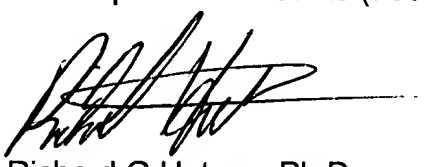
One of ordinary skill in the art at the time of filing would have been motivated to use the methods taught by Rao et al. to isolate an enriched or purified preparation of

human mitotic oligodendrocyte progenitor cells from humans so that these pure cell preparations could be used to treat neurological disorders in humans, such as. Parkinson's Disease, such as by transplantation of such cells into an afflicted individual. This motivation is suggested by Rao et al. and the reasonable expectation of success comes from the results of Rao et al. who successfully isolated such an enriched or purified preparation of mitotic oligodendrocyte progenitor cells from rat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
May 30, 2003